

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Investigating the effectiveness of intratympanic corticosteroid treatment in comparison with standard treatment on hearing condition in adults with serous otitis

Protocol summary

Study aim

Determining and comparing the effectiveness of intratympanic corticosteroids in comparison with standard treatment on patients' hearing status - Determining and comparing the effectiveness of intratympanic corticosteroids in comparison with standard treatment on the tympanogram status of patients

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 72 patients. The order of referral was used for randomization.

Settings and conduct

The study is conducted in Taleghani Hospital, Tehran, in the Otolaryngology Clinic

Participants/Inclusion and exclusion criteria

In this study, all adult patients over 12 years of age with unilateral or bilateral serous otitis who referred to Taleghani Hospital from 1402 to 1403 will be examined. In this study, adult patients with serous otitis, who have a gap of 10-30 dB in the PTA test and have a type B tympanometry, and after one month from the onset of the disease, there is still no change in PTA and tympanometry, are included in the study. Treatment is done after sinus endoscopy and sampling.

Intervention groups

For treatment, in the control group standard treatment (treatment with saline irrigation 4 times a day and inhaled fluticasone nasal spray 125 micrograms/dose in the form of bilateral puffs every 12 hours and follow-up) and in the study group, in addition to receiving standard treatment similar to the injection control group Cortone (methylprednisolone 50 mg) is injected intratympanically under local anesthesia with lidocaine mesh for patients, and then follow-up is done with PTA test and tympanometry every month for up to three months. And finally, the results are compared with the group that only

received the standard treatment

Main outcome variables

More complete treatment for serous otitis and prevention of the need for surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240108060650N1**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Keyarmin Ghavam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8809 8140

Email address

kagh7495@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2025-02-18, 1403/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of intratympanic corticosteroid treatment in comparison with standard treatment on hearing condition in adults with serous otitis

Public title
Intratympanic corticosteroids in serous otitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral or bilateral serous otitis Gap between 10-30 in PTA Type B tympanometry Failure to improve within a month of the onset of symptoms
Exclusion criteria:
Reluctance to participate in a clinical study
Nasopharyngeal carcinoma Systemic corticosteroids use

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization In this way, the first two clients are in the intervention group and the next two are in the control group

Blinding (investigator's opinion)
Double blinded

Blinding description
Neither the participating patients nor the attending physician know in which group the patients will be randomized

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Medicine, Shahid Beheshti University of Medical Sciences
Street address
Yadegar imam highway , isargaran, 3rdfarhang , number 14
City
Tehran
Province
Tehran
Postal code
1981776397

Approval date
2024-01-01, 1402/10/11

Ethics committee reference number
IR.SBMU.MSP.REC.1402.518

Health conditions studied

1

Description of health condition studied
Serous otitis

ICD-10 code
H65.0

ICD-10 code description
Acute serous otitis media

Primary outcomes

1

Description
Gap in audiometry

Timepoint
One month and three month after treatment

Method of measurement
Audiometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to receiving the same standard treatment as the control group, the study group receives intratympanic corticosteroid injection (methylprednisolone 50 mg) under local anesthesia with lidocaine mesh.

Category
Treatment - Drugs

2

Description

Control group: In the control group, standard treatment (treatment with saline irrigation 4 times a day and inhalation fluticasone nasal spray 125 micrograms/dose in the form of bilateral puffs every 12 hours and follow-up)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Keyarmin Ghavam

Street address

Velenjak, taleghani hospial

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1416613675

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Keyarmin Ghavam

Street address

Yadegar imam,isargaran, 3rd farhang, No 14

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Keyarmin Ghavam

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Fax**Email**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available